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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,757	12/08/2000	David Mack	05882.0185.CPUS01	2797
27194	7590	04/09/2004	EXAMINER	
HOWREY SIMON ARNOLD & WHITE, LLP			HELMS, LARRY RONALD	
BOX 34			ART UNIT	
301 RAVENSWOOD AVE.			PAPER NUMBER	
MENLO PARK, CA 94025			1642	
DATE MAILED: 04/09/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/733,757

Applicant(s)

MACK ET AL.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-40, 42 and 43 is/are rejected.
- 7) ☒ Claim(s) 41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claim 41 has been amended.
2. Claims 32-43 are pending and under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

### ***Rejections Withdrawn***

4. The rejection of claim 41 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendment to the claim.
5. The rejection of claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claim.
6. The rejection of claim 41 under 35 U.S.C. 112, first paragraph is withdrawn.

### ***Response to Arguments***

7. The rejection of claims 32-40 and 42-43 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

Art Unit: 1642

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The response filed 12/16/03 has been carefully considered but is deemed not to be persuasive. The response states that the specification provides adequate written description for a method with a nucleic acid sequence that is at least 95% identical to SEQ ID NO:1 and SEQ ID NO:1 is 2103 nucleotides long and The specification "teaches nearly the entire sequence of the nucleic acid: it has at least 95% sequence identity with the SEQ ID NO:1" (see page 5 of response). In response to this argument, it appears that applicants admit that they are not in possession of the entire sequence of SEQ ID NO:1 and as such how could the specification teach something that is not taught? The response states that the DNA encoding CBK8 as depicted in SEQ ID NO:1 contains a Pleckstrin domain and that a CBK8 allele or variant would contain a Pleckstrin domain and the sequence of AW136973 shares 98.2% identity to SEQ ID NO:1 (see page 6). In response to this argument, it is immaterial that the specification teaches a sequence that is 98.2% identical to SEQ ID NO:1 wherein the specification does not teach that the AW136973 sequence is expressed at a higher level in colorectal cancer. In addition, it does not matter if the sequence has a Pleckstrin domain because the claims do not require this part of the nucleic acid or protein to have this domain. It has not been shown that this domain is even important for the function of the protein, what ever it is. The response argues the case law and the examiner acknowledges this (see page 6-7). The response states that the claims are similar to those of Example 14 in the Revised Interim Written Description Guidelines Training Materials and that

example 14 is to a protein that is 95% identical to SEQ ID NO:3 and catalyze the reaction of A to B. The response states that the present situation is similar in that it exemplifies the nucleotide sequence having SEQ ID NO:1 that is characterized by differential expression in colorectal cancer and the specification teaches how to make variants and assaying for expression. (see page7 of response). In response to this argument, example 14 is to a protein that has a function that can be assayed by catalyzing A to B. It is clear that the protein has a catalytic domain that when intact can function to catalyze A to B and one skill in the art would know where or which area or domain to alter and still retain activity. This is not the situation in the claimed invention, there is no area of the nucleic acid or the protein identified that would allow for functioning of the protein or which area of the nucleic acid would be maintained in order to have it "over expressed in cancer cells". The only species identified in the specification is SEQ ID NO:1 as being over expressed in colorectal cancer.

Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

8. The rejection of claims 32-40, 42-43 under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 12/16/03 has been carefully considered but is deemed not to be persuasive. The response states that it is merely a matter of routine experimentation to determine what nucleic acid sequences are at least 95% identical to SEQ ID NO:1

Art Unit: 1642

and to determine whether the nucleic acid is differentially expressed in colorectal cancer and the response states that SEQ ID NO:1 is at least 95% identical to SEQ ID NO:1 (see page 9 of response). In response to this argument, while it may be routine to determine which sequences are 95% to SEQ ID NO:1 or to make nucleic acids that are 95% to SEQ ID NO:1, it is not routine to determine if the nucleic acid is over expressed in colorectal cancer. It is not known if just any nucleic acid that is 95% to SEQ ID NO:1 is in colorectal cancer or if it exists or can be used to diagnose colorectal cancer. Just because the specification teaches SEQ ID NO:1 does not enable any nucleic acid that is at least 95% to SEQ ID NO:1 for diagnosis of colorectal cancer.

### ***Conclusion***

9. No claim is allowed. Claim 41 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1642

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



**LARRY R. HELMS, PH.D**  
**PRIMARY EXAMINER**